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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,348	05/09/2005	Karen Silence	A0848.70005US00	4929

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,348	SILENCE ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-21,26,28,30,34,36,38-41 and 44-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13,15-21,26,28,30,34,36,38-41 and 44-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 3-8, 10, 12, 13, 15-21, 26, 28, 30, 34, 36, 38-41 and 44-47 have been amended and claims 14, 22-25, 27, 29, 31-33, 35, 37, 42, 43 and 49 have been canceled as requested in the preliminary amendment filed on 09 May 2005. Following the amendment, claims 1-13, 15-21, 26, 28, 30, 34, 36, 38-41 and 44-48 are pending in the instant application.

Claims 1-13, 15-21, 26, 28, 30, 34, 36, 38-41 and 44-48 are under examination in the instant office action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Each of Groups I-XVIII, claim(s) 1-13, 15, 16, 21 and 40, is drawn to one of the anti-TNF-alpha polypeptides corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups XIX-XXXVI, claim(s) 17, is drawn to a nucleic acid sequence encoding an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups XXXVII-LIV, claim(s) 18-20, is drawn to a method of identifying an agent that modulates the binding of an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups LV-LXXII, claim(s) 26, 28, 30, 34, 36, 38, 39 and 45, is drawn to a method for treating and/or preventing and/or alleviating disorders relating to inflammatory reactions comprising administering to a subject in need of such treatment an effective amount of an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups LXXIII-XC, claim(s) 41, is drawn to a method of diagnosing a disorder characterized by the dysfunction of Tumor Necrosis Factor-alpha comprising contacting a sample with an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups XCI-CVIII, claim(s) 44, is drawn to a method for purification of Tumor Necrosis Factor-alpha, comprising contacting a sample with an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

Each of Groups CIX-CXXVI, claim(s) 46-48, is drawn to a method for producing an anti-TNF-alpha polypeptide corresponding to a sequence represented by one of SEQ ID NOs: 30-43 and 73-76, respectively.

The inventions listed as Groups I-CXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I-CXXVI is that they all relate to an anti-TNF-alpha polypeptide comprising at least one anti-TNF-alpha single domain antibody. However, WO 91/02078A1 to Rathjen et al. (Cite No. B5 on IDS dated 11 September 2006) teaches ligands that bind to TNF-alpha and alter its biological activity, including single domain antibodies (see abstract). Thus, the technical feature linking the inventions of Groups I-CXXVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Routes of administration:

a. Vaginal tract

b. Rectal tract

c. Nose

d. Upper respiratory tract

e. Lung

f. Intestinal mucosa

g. Sublingual

h. Transdermal

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 26, 28, 30, 34, 36, 38, 39 and 45.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to divergent administration techniques and the use of one does not require the use of any other technique.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Disorders:

i. Inflammation

j. Rheumatoid arthritis

k. Crohn's disease

l. Ulcerative colitis

m. Inflammatory bowel syndrome

n. Multiple sclerosis

o. Addison's disease

p. Autoimmune hepatitis

q. Autoimmune parotitis

r. Diabetes Type I

s. Epididymitis

t. Glomerulonephritis

u. Graves' disease

v. Guillain-Barre syndrome

w. Hashimoto's disease

x. Hemolytic anemia

y. Systemic lupus erythematosus

z. Male infertility

aa. Multiple sclerosis

bb. Myasthenia Gravis

cc. Pemphigus

dd. Psoriasis

ee. Rheumatic fever

ff. Rheumatoid arthritis

gg. Sarcoidosis

hh. Scleroderma

ii. Sjogren's syndrome

jj. Spondyloarthropathies

kk. Thyroiditis

ll. Vasculitis

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 26, 28, 30, 34, 36, 38, 39, 41 and 45.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to a plurality of disease states with different etiologies, symptoms and treatments.

Applicants are advised that the reply to this requirement to be complete must include (i) elections of species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

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Patent Examiner
Art Unit 1649
21 August 2007

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646